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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,192

09/08/2003

Mark J. Cooper

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SUITE 1200

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EXAMINER

LONG, SCOTT

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

10/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,192	COOPER ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,8-14,17-19,26,28,30,31,34,35,38-40,51-55,58-70,73-82,103,104,106,107,114,115 and 122.

Continuation of Disposition of Claims: Claims rejected are 1-5,8-14,17-19,26,28,30,31,34,35,38-40,51-55,58-70,73-82,103,104,106,107,114,115 and 122.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 15 July 2008.

Claim Status

Claims 6-7, 15-16, 20-25, 27, 29, 32-33, 36-37, 41-50, 56-57, 71-72, 83-102, 105, 108-113, 116-121, and 123 are cancelled. Claims 1-5, 8-14, 17-19, 26, 28, 30-31, 34-35, 38-40, 51-55, 58-70, 73-82, 103-104, 106-107, 114-115, and 122 are under current examination.

Priority

This application claims benefit from U.S. Application No. 2002/0042388 (abandoned), filed 31 May 2001, provisional U.S. provisional Application No. 60/287,419, filed 31 May 2001, and U.S. provisional Application No. 60/207,949, filed 31 May 2000. The instant application has been granted the benefit date, 31 May 2000, from the application 60/207,949. However, the examiner notes that the provisional application makes no mention of lyophilization or disaccharides.

Response to Amendments - Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 8-9, 11-12, 17-18, 26, 28, 30, 34, 36, 38, 53, 65, 78, 85, 92 and 102-103 remain rejected under 35 USC 102 as anticipated by Hanson et al. (US-5,844,107) for the reasons of record and the comments below.

Applicant's arguments (Remarks, pages 12-14, filed 7/15/2008), have been fully considered but they are unpersuasive.

Fundamentally, the dispute between the applicant's position and the examiner's position is about the nature of the rod-like structures of Hanson and the instant claims. The examiner has asserted throughout the prosecution history that rods and toroids are both inherently present in the nucleic acid formulations like those of Hanson and the instant application. The applicant's representative has asserted "The relaxed toroids of neither Hanson nor the present application are the same as the recited rods of condensed nucleic acid" (Remarks, page 13, lines 10-11). The attempt to overcome all the other teachings of Hanson by arguing over inexact language such as "relaxed toroids" and "rods" seems to the examiner to be merely sophistry. The examiner has

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included a review article (Martin et al. FEBS Letters. 2000; 480: 106-112) for the applicant's representative which describes the relationship between rods and toroids in nucleic acid formulations like those of Hanson and the instant application. The examiner assumes that the inventors were already aware of the nature of nucleic acid condensation which produces both rods and toroids. In Martin et al., particularly Section 3.3, "Dynamic formation of toroidal and rod-like condensates," the references indicates that rods and toroids are interchangeable forms of condensed DNA, "ring and rod-like structures exist dynamically, having the ability to reversibly equilibrate between structures" (page 111, col.1, parag.3). Essentially, it is impossible to have a pure population of either toroids or rods when DNA is condensed as by Hanson or the instant specification. The way a particular artisan may refer to this process can include the term "relaxed toroid" as referring to "rod." Although the applicant's representative asserts that there is a difference between these two terms, she does not provide evidence or specific definitions from the specification to indicate that this is true.

The examiner believes it is worth reviewing the same arguments presented in earlier actions: Hanson teaches "electron microscopic results have been indicated as follows:...the structure resulting from condensation are rod-like relaxed toroids of increased size" (col.62, lines 51-57). This teaching is remarkably similar to that of the instant application, "DNA condensed with acetate and bicarbonate salts of CK30 polylysine assumed forms of long (100-300 nm) and narrow (10-20 nm) rods and relaxed toroids (~50-100 nm diameter, 10-20 nm width)" (specification, page 16, lines 1-3). Since Hanson teaches compositions comprising condensed DNA/polylysine

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cation/acetate counterion complexes and at least a subset of these complexes are rod-shaped as visualized by electron microscopy and Hanson further teaches that the shape of these condensed complexes is due in part to the salt concentrations, the examiner believes that the rod-like, relaxed toroids of Hanson satisfy the claim limitations of the instant application, since all the other conditions required by the instant claims are taught by Hanson et al. and “rod-like” structures are inherent to such formulations.

While the patent rules and laws allow the applicant to utilize whatever language pleases him, introducing a broad term such as “rod” into the claims cannot negate all the other teachings provided by Hanson et al. The applicant must clearly distinguish his invention from the prior art. It is the examiner’s opinion, that arguing over the word, “rod,” will not make the current claims allowable. Without a doubt, Hanson et al. anticipate every limitation regarding the nature of polycation molecules, counterions, and DNA condensation. Hanson also seems to note the “rod-like” shape of the complexes. Even if Hanson did not describe the shape of the molecules to the satisfaction of the applicant, it is inherent to create such rod-shaped complexes when complexing nucleic acids in the manner of the instant claims and methods of Hanson et al. The examiner finds the applicant’s arguments unpersuasive.

Accordingly, the examiner hereby maintains the rejection of the instant claims as anticipated by Hanson et al.

Response to Amendments - Claim Rejections 35 USC § 102

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 10, 19, 31, 35, 37, 51-53, 63-65, 67-68, 76-78 and 104 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson et al. (US Patent 5,844,107) in view of Park et al. (US Patent 6,177,274) and Schacht et al. (WO/1998/19710).

Claims 58-62, 66, 73-75, 79-82, 122 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson et al. (US Patent 5,844,107) in view of Park et al. (US Patent 6,177,274) and further in view of Schacht et al. (WO/1998/19710) as applied to claims 3, 10, 19, 31, 35, 37, 51-53, 63-65, 67-68, 76-78 and 104 above, and further in view of Mao et al. (Journal of Controlled Release 70 (2001) 399–421).

Claims 4-7, 13-16, 39-42, 54-57, 69-72, 106-109, and 114-117 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson et al. (US Patent 5,844,107) in view of Park et al. (US Patent 6,177,274) and further in view of Schacht et al. (WO/1998/19710) as applied to claims 3, 10, 19, 31, 35, 37, 51-53, 63-65, 67-68, 76-78 and 104 above, and further in view Kwoh et al. (Biochimica et Biophysica Acta 1444 (1999) 171-190).

Applicant's arguments (Remarks, pages 15-16), have been fully considered but they are unpersuasive.

Primarily, the applicant has argued that Hanson does not teach rod-shaped complexes and the secondary references are insufficient when combined with Hanson to result in rod-shaped complexes. As the examiner described above, rod-shaped complexes normally occur in formulations like those of Hanson et al.

The examiner finds the applicant's argument unpersuasive and hereby maintains the rejection of the instant claims under 35 USC 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner, Art Unit 1633
/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633